

STATE OF MINNESOTA

DISTRICT COURT

COUNTY OF RAMSEY

SECOND JUDICIAL DISTRICT

CIVIL DIVISION

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In Re Minnesota State Court Guidant Corp.  
Implantable Defibrillators Product Liability  
Litigation.

**ORDER 3**

Court File No.: 62-C4-06-006672

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**PRESERVATION OF EVIDENCE**

Pursuant to the parties' agreement for an order to preserve evidence, and pursuant to the court's inherent power, this Court issues the following Order. References to "this litigation" in this Order are to the above-captioned matter unless otherwise qualified. This order is to be read in conjunction with the other Orders of this Court.

IT IS ORDERED:

**Device Preservation**

A. Defendants, and their officers, employees, agents and attorneys, shall not destroy, dispose of, alter, remove, or destructively test any physical evidence relevant to Plaintiffs' alleged defects in the VENTAK PRIZM 2 DR, Model 1861; VENTAK PRIZM AVT Model 1900; VITALITY AVT Models A135 and A155; CONTAK RENEWAL 3 AVT Models M150, M155; CONTAK RENEWAL 3 AVT HE Models M157, M159; CONTAK RENEWAL 4 AVT, Models M170, 175; CONTAK RENEWAL 4 AVT HE Models M177, M179; CONTAK RENEWAL Model H135; CONTAK RENEWAL 2 Model H155; PULSAR MAX Models 1170, 1171, 1270; PULSAR Models 0470, 0870, 0970, 0972, 1172, 1272; DISCOVERY Models 1174,

1175, 1273, 1274, 1275; MERIDIAN Models 0476, 0976, 1176, 1276; PULSAR MAX II Models 1180, 1181, 1280; DISCOVERY II Models 0481, 0981, 1184, 1186, 1187, 1283, 1284, 1285, 1286; CONTAK TR Model 1241; VIRTUS PLUS II Models 1380, 1480; INTELIS II Models 1483, 1484, 1485, 1384, 1385, 1349, 1499; INSIGNIA Entra SSI Models 0484, 0485; INSIGNIA Entra DDD Models 0985, 0986; INSIGNIA Entra SR Models 1195, 1198; INSIGNIA Entra DR Models 1294, 1295, 1296; INSIGNIA Ultra SR Model 1190; INSIGNIA Ultra DR Models 1290, 1291; INSIGNIA Plus SR Model 1194; INSIGNIA Plus DR Models 1297, 1298; INSIGNIA AVT SSI Model 482; INSIGNIA AVT VDD Model 882; INSIGNIA AVT DDD Model 982; INSIGNIA AVT SR 1192; INSIGNIA AVT DR 1292; NEXUS Entra SSI Models 1325, 1326; NEXUS Entra DDD Models 1425, 1426; NEXUS Entra SR Models 1395, 1398; NEXUS Entra DR Models 1466, 1494, 1495; NEXUS Ultra SR Model 1390; NEXUS Ultra DR Models 1490, 1491; NEXUS Plus SR Model 1394; NEXUS Plus DR Models 1467, 1468; NEXUS AVT SSI Model 1328; NEXUS AVT VDD Model 1428; NEXUS AVT DDD Model 1432; NEXUS AVT SR Model 1392; NEXUS AVT DR Model 1492; CONTAK RENEWAL 3 Models H170, H173, H175; CONTAK RENEWAL 3 HE Models H177, H179; CONTAK RENEWAL 4 Models H190, H195; CONTAK RENEWAL 4 HE Models H197, H199; RENEWAL RF Models H230, H235; RENEWAL RF HE Model H239; CONTAK RENEWAL 3 RF Models H210, H215; CONTAK RENEWAL 3 RF HE Models H217, H219; CONTAK RENEWAL 4 RF Models H230, H235; CONTAK RENEWAL 4 RF HE Model H239; CONTAK RENEWAL TR Models H120, H125; CONTAK RENEWAL TR 2 Models H140, H145; VENTAK PRIZM 2 Models 1860, 1861; VITALITY HE Model T180; VITALITY Models 1870, 1871, T125, T127, T135; VITALITY 2 Models T165, T167, T175, T177; VITALITY DS DR Model T 125; VITALITY 2VR Model T175; VITALITY DS; and

VITALITY 2DR Model T165 and including the following related devices: VENTAK PRIZM VR Model 1850; VENTAK PRIZM DR Model 1851; VENTAK PRIZM VR HE Model 1852; VENTAK PRIZM DR HE Model 1853; VENTAK PRIZM VR HE Model 1857; and VENTAK PRIZM DR HE Model 1858; or other devices otherwise part of this litigation.

If the parties conduct any testing or analysis of such devices, they shall ensure that electronic data regarding patient-specific information and system diagnostics stored in the devices is preserved. It is not necessary to download generic program codes from each individual device.

When devices identified in the preceding paragraph are surgically removed, Defendants' representatives who are present at removal shall perform, or use their best efforts to request that physicians perform, a "Save to Disk" function before removal, and shall ensure that data saved to a computer disk or other memory device is preserved intact pending further order of this Court or another court with jurisdiction. In the event that explanted devices are placed in the custody of a Defendant, the Defendant shall ensure that the devices are saved in a manner that preserves their electronic integrity and the integrity of any data and/or program code contained in the devices, shall label the device with identifying patient information and the date and location of the explant procedure, and shall store the devices at room temperature away from strong magnetic fields.

This order shall not prohibit the following testing under the conditions specified:

- (1) Conducting electrical tests of returned devices after the preservation of electronic data described in paragraph (A). Where there is visual evidence of polyimide degradation, X-rays or other visual recording shall be taken and preserved. In the ordinary course, such testing should not alter or destroy evidence.

- (2) Erasing memory to perform electrical testing where the memory to be erased is

already otherwise preserved.

(3) Destructive testing specifically requested by the FDA, or otherwise necessary to a Defendant's CAPA, provided that the Defendant maintains an adequate written, and where applicable, visual record of the testing. The results of such testing, including data and analysis of such testing, shall be made equally available to all parties.

(4) Testing required to comply with regulations of a foreign government within its jurisdiction, provided that Defendants maintain an adequate written, and where applicable, photographic record of such testing.

(5) Destructive testing of Ventak Prizm 2 DR 1861, manufactured prior to April 16, 2002, pursuant to Defendants' obligations under 21 CFR § 820.198 where the device does not manifest arcing in the header as described in Guidant's press release of June 17, 2005, but is alleged to have performed out of specifications in the field or in the lab. The results of such testing, including data and analysis of such testing, shall be made equally available to all parties. Defendants shall maintain an adequate written and, where applicable, visual record of any such testing.

(6) Destructive testing of Contak Renewal or Contak Renewal 2, manufactured prior to August 26, 2004, pursuant to Defendants' obligations under 21 CFR § 820.198 where the device does not manifest arcing in the header as described in Guidant's press release of June 17, 2005, but is alleged to have performed out of specifications in the field or in the lab. The results of such testing, including data and analysis of such testing, shall be made equally available to all parties. Defendants shall maintain an adequate written and, where applicable, visual record of any such testing.

(7) Destructive testing of Ventak Prizm AVT, Vitality AVT, Contak Renewal AVT,

Contak Renewal 3 AVT or Contak Renewal 4 AVT pursuant to Guidant's obligations under 21 CFR § 820.198 where the device does not manifest latching as described in Guidant's press release of June 17, 2005, but is alleged to have performed out of specifications in the field or in the lab. The results of such testing, including data and analysis of such testing, shall be made equally available to all parties. Defendants shall maintain an adequate written and, where applicable, visual record of any such testing. Further, if an AVT device demonstrates latching upon return, Defendants may issue a reset command to the device to pull it out of the loop, enable interrogation with programmer hardware, and enable the printing of reports and generation of patient data disks which will contain details of the final episodes. (The court expects that with this approach only the loop will be terminated, and no data will be lost. If the devices are left in a latched state, the batteries will deplete in a few months.)

(8) Destructive testing of a Contak Renewal 3, Contak Renewal 4, Contak Renewal 3 AVT, Contak Renewal 4 AVT, or Renewal RF pursuant to Defendants' obligations under 21 CFR § 820.198 where the device manifests a micro-switch issue as described in Guidant's press release of June 23, 2005. As to such testing, Defendants shall open the case halves of the pulse generator to access the component, obtain an x-ray image and photograph of the component, measure the switch, and probe the switch to assess its performance. Destructive testing of the switch itself shall not occur.

This order shall not prohibit destructive testing of a Contak Renewal 3, Contak Renewal 4, Contak Renewal 3 AVT, Contak Renewal 4 AVT or Renewal RF where the device does not manifest a micro-switch issue as described in Guidant's press release of June 23, 2005, but is alleged to have performed out of specifications in the field or in the lab. The results of such

testing, including data and analysis of such testing, shall be made equally available to all parties. Defendants shall maintain an adequate written and, where applicable, visual record of any such testing.

B. A Defendant may re-institute its ordinary device-retention policy for devices not specified in paragraph A or otherwise not subject to litigation.

C This order does not prohibit the return of a device listed in Paragraph A to a patient or patient representative pursuant to a patient request.

D. Any patient who is a Plaintiff in any action subject to this order (including plaintiffs in any action who have agreed to coordinate discovery with this litigation) and who has an explanted device shall:

(1) Within sixty (60) days of the entry of this order, provide Defendants with the model number and serial number for tracking purposes;

(2) Provide Defendants an opportunity to perform a "Save to Disk" and "Hex Dump" download within thirty (30) days after either entry of this order, or from the date the patient comes into possession of the device, whichever is later;

(3) Not destroy, dispose, alter, remove or destructively test any such device, pending further order of this court for testing of explanted devices;

(4) Provide Defendants an opportunity to have a designated representative visually inspect the device at a mutually convenient time and place;

(5) Not allow a Plaintiff consultant or expert to perform any analysis or testing of a device prior to giving Defendants an opportunity to conduct a physical inspection of the device in the presence of Plaintiff or Plaintiff's representatives, and give Defendants an opportunity to be present during, and to record, any analysis or testing.

A Plaintiff in this litigation who has been in possession of an explanted device prior to the date of this Order shall comply with the requirements of this paragraph C and its subparts.

### **Document Preservation**

E. The parties, and their officers, employees, agents and attorneys, shall not purge data; delete data; erase disks, tapes or electronic files of any kind; erase memory; or otherwise alter, change, modify or destroy information (including any meta data) stored in or by computer (regardless of whether that information is created and/or stored before or after the entry of this order) relevant to Plaintiffs' claims of alleged defects in the device models specified in Paragraph A, and relevant to Defendants' defenses. This Order shall not prohibit the following actions:

(1) E-mail:

(a) Reuse of incremental and/or daily tapes as part of tape rotation where full back-up tapes are being retained for all e-mail servers worldwide which are cumulative of changes over time.

(b) Deletion of e-mail from the date of this Order by individuals whose accounts are journaled, which means that every e-mail sent or received by these people is captured and placed in a secure location.

(c) Deletion of e-mail before the date of this Order by individuals whose accounts have been archived to a secure vault for discovery purposes, provided that such archiving must include not only such individuals' in-box but also any other folders or archives of saved e-mail received or sent by such individuals.

(d) Application of normal tape retention of e-mail server tapes after the archiving has been completed, if the archiving and journaling process includes all individuals whose e-mails are encompassed by the e-mail server tapes.

(2) Project Netware Share Files: Re-use of incremental and/or daily tapes as part of tape rotation where full back-up tapes for the project network file shares are being retained. The R&D share files in St. Paul have been locked-down for change.

(3) Network Home Directories: Re-use of incremental and/or daily tapes as part of the Company's tape rotation where full back-up tapes for the Network Home directories (U:\ drives) are being retained.

(4) Application(s) / System(s):

(a) Re-use of incremental and/or daily tapes where full back-up tapes for the applicable applications / systems are being retained.

(b) Changing applications as required to conduct business (primarily adding functionality) where the application team has been contacted, is managing a log of all such changes to the application, and is maintaining copies of source and object code for all versions of the applications.

F. The parties, and their officers, employees, agents and attorneys, shall preserve software and programs written for the devices, including but not limited to software and programs to obtain, manage, read, or manipulate data from patient data disks.

G. The parties, and their officers, employees, agents and attorneys, shall preserve information contained or represented on patient data disks, and on laptop computers (including those used by doctor/field representatives), and information exchanged on VPN networks relating to the devices listed in paragraph A.



H. The parties, and their officers, employees, agents or attorneys, shall not shred, change, modify, alter, remove, destroy, sanitize, or otherwise dispose of documents, photographs, videotapes, or any other type of documentary evidence of information relevant to Plaintiffs' claims of alleged defects in the device models specified in paragraph A, or relevant to Defendants' defenses.

I. Defendants may destroy or otherwise alter specified documents due to routine policy or programs after providing specific and detailed written notice to all parties, including information as to the routine policy or program that applies and identification of the documents or categories thereof, if no other party, personally or through counsel, notifies Defendants in writing of its objections within thirty (30) days after notice is mailed or otherwise transmitted. If an objection is raised, the parties may raise the issue with this court or any other court with jurisdiction, and shall preserve the documents in question pending resolution by the Court.

J. The parties, without leave of court, may agree in writing that certain documents or categories of documents or evidence need not be preserved as otherwise required by this Order. If such agreement is reached, such agreement is effective upon signing and without further order of this Court.

K. This Order shall not be deemed to create any "safe harbors" for the destruction of evidence. If it is determined by this Court that evidence has been destroyed or lost, whether knowingly or not, appropriate sanctions will be imposed.

L. Each party shall bear its own costs for complying with this Order.

October 30, 2006

  
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William H. Leary III  
Judge of the District Court